

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION

BAYER HEALTHCARE  
PHARMACEUTICALS, INC. and DOW  
PHARMACEUTICAL SCIENCES, INC.,

Plaintiffs,

v.

RIVER'S EDGE PHARMACEUTICALS,  
LLC, and TERESINA HOLDINGS, LLC,  
MEDICAL PRODUCTS  
LABORATORIES, INC. AND STAYMA  
CONSULTING SERVICES, LLC

Defendants.

Case No.: 11-cv-01634-LMM

**DEFENDANTS' OBJECTION TO THE SPECIAL MASTER'S  
REPORT AND RECOMMENDATION ON SUPPLEMENTAL CLAM  
CONSTRUCTION**

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## **STATUTES**

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Pursuant to Federal Rule of Civil Procedure 53(f) and this Court's Order (Dkt. 398 at 7), Defendants object to the Special Master's Report and Recommendation on Supplemental Claim Construction (Dkt. 541) ("Recommendation").

## **I. INTRODUCTION**

The Special Master's second recommended construction of the final remaining term in dispute, "lightly crosslinked polyacrylic acid polymer" (the "Lightly Crosslinked Limitation") – a construction not proposed, considered or briefed by either party – should be rejected for four reasons.

First, the Special Master failed to apply the more rigorous indefiniteness standard articulated by the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2130 (2014). In *Nautilus*, the Supreme Court held that the prior Federal Circuit threshold requiring only that a claim be “amenable to construction” and not “insolubly ambiguous” was insufficient to satisfy the definiteness requirement of 35 U.S.C. § 112. Instead, a “reasonable certainty” standard was articulated for claim definiteness: “In place of the ‘insolubly ambiguous’ standard, we hold that a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution

history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus*, 134 S. Ct. at 2123.

Prior to *Nautilus*, the Federal Circuit would find a claim indefinite when “a claim [was] insolubly ambiguous, and no narrowing construction can properly be adopted”, this was so “even though the task [of construction] may be formidable and the conclusion may be one over which reasonable persons will disagree”, that was still “sufficiently clear to avoid invalidity on indefiniteness ground.”<sup>1</sup> The *Nautilus* Court explained “[i]t cannot be sufficient that a court can ascribe *some* meaning to a patent's claim; the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters *post hoc*.”<sup>2</sup>

In contrast to the Supreme Court's guidance and this Court's Order, the Special Master's statements show that she believed that she was under mandate of this Court to come up with *some* construction. (Exhibit A at 151: 3-5; 162 3-5). The recommended or proposed construction was the result of her efforts to “thread” together the teachings of third-party patents and expert testimony. (Exhibit A, 155:18-156:2). The Special Master's recommended construction is

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<sup>1</sup> *Dow Chem. Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620, 630 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2452, 195 L. Ed. 2d 264 (2016).

<sup>2</sup> *Id.* at 2130 (emphasis in original).



precisely the kind of *post hoc* attempt to ascribe *some* meaning to an otherwise ambiguous claim term that the Supreme Court rejected in *Nautilus*.

Second, the Special Master erred by adopting one of many possible constructions for the Lightly Crosslinked Limitation. The construction now recommended by Special Master is not, according to Plaintiff's expert, the best construction of the term. (Exhibit A, 143 -145). Instead, the construction is a fusion of the Special Master's proposed construction and the Plaintiff's initial proposed construction, both of which were rejected by this Court (Dkt. 490, 530).

Third, the Special Master's proposed construction is unsupported by and in conflict with the intrinsic evidence, which provides no objective standard to measure a term of degree - "lightly." The Special Master's construction incorporates a weight-to-weight percentage measurement she herself previously rejected as conclusory, unsupported by the intrinsic or extrinsic evidence and at odds with the claims themselves. (Dkt. 456 at 46). The Special Master compounds this error by adopting a construction that violates claim construction principals by importing numeric ranges derived from a metric that is nowhere in the '383 Patent.

Finally, the Special Master erred by failing to find the Lightly Crosslinked Limitation term indefinite. *Nautilus* and its progeny compel a finding of

indefiniteness. Indeed, two high-profile Federal Circuit cases – *Teva*<sup>3</sup> and *Dow*<sup>4</sup> – held patents indefinite under the new *Nautilus* standard notwithstanding that the same patents were previously found definite under pre-*Nautilus* law. Moreover, critical to the issues here, in each instance the Federal Circuit held the patents indefinite because the patent's intrinsic record did not disclose what measurement technique to use to test for the relevant claim limitation. Without this information, the patents were not “precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them.” *Dow*, 803 F.3d at 630 (citing *Nautilus*).

For the foregoing reasons, set forth more fully herein, the Court should not adopt the recommendation and find that the Lightly Crosslinked Limitation is indefinite.

## II. BRIEF STATEMENT OF UNDISPUTED FACTS

The claim construction history in this case has been extensive.<sup>5</sup> The construction now recommended by the Special Master is the *ninth* construction advanced by litigants and courts confronted with task of construing the Lightly Crosslinked Limitation. *See below*.

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<sup>3</sup> *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015)

<sup>4</sup> *Dow Chemical Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620 (Fed. Cir. 2015)

<sup>5</sup> (Dkt. 530 at 1).

In *Medicis Pharmaceutical Corp. et al. v. Actavis Mid Atlantic LLC*, No 11-409, LPS-CJB (D. Del) ("Medicis"), prior plaintiffs (which included Plaintiff Dow) proposed another construction for the Lightly Crosslinked limitation, which they supported with expert testimony, prior defendants proposed another construction, also supported by expert testimony. In a decision issued prior to *Nautilus*, the Delaware District Court ultimately adopted a construction that differs significantly from Plaintiffs' proposed construction in this case. Plaintiffs have rejected all constructions presented and ordered in *Medicis*. (See Plaintiffs' Opening Markman Brief, Dkt. 121, p. 22, n. 6).

The nine different constructions that have been presented for the Lightly Crosslinked Limitation are shown below.

No.	Party/Case	Construction of Lightly Crosslinked limitation
1	Plaintiffs' proposed construction in the <i>Medicis</i> case on February 23, 2012	plain and ordinary meaning (1:11-cv-00409-LPS (D.Del.) [Dkt. 51] at 11., <b>Exhibit "B"</b> )
2	Prior Defendants in <i>Medicis</i> case	a cross-linked polyacrylic acid polymer with a viscosity of less than 15,000 cP (1:11-cv-00409-LPS (D.Del.) [Dkt. 51] at 11.)
3	Prior Defendants in <i>Medicis</i> case	a cross-linked polyacrylic acid polymer with a viscosity of less than 15,000 cP where the polymer is in a 0.5% solution at pH 7.5 and the viscosity is measured with a Brookfield viscometer at 20 rpm. (1:11-cv-00409-LPS (D.Del.) [Dkt. 98] at 6., <b>Exhibit "C"</b> ).

No.	Party/Case	Construction of Lightly Crosslinked limitation
4	Court's construction in <i>Medicis</i> case	a cross-linked polyacrylic acid polymer with a viscosity of less than about 15,000 cP where the polymer is in a 0.5% solution at pH 7.5 and the viscosity is measured with a Brookfield viscometer at 20 rpm. (1:11-cv-00409-LPS (D.Del.) [Dkt. 143] at ¶ 3)( <b>Exhibit "D"</b> )
5	Plaintiffs' proposed construction in this case on August 24, 2014	plain and ordinary meaning, which is: "a polyacrylic acid polymer cross-linked with a suitable cross-linking agent (cross-linker) at an amount less than about 5-10% (w/w) (Dkt. 104-1 at 3)
6	Plaintiffs' proposed construction in this case on October 27, 2015	A gelling agent made from polyacrylic acid which has been cross-linked with a suitable crosslinking agent (crosslinker) at an amount less than 5% (w/w) to form a non-dimensionally stable material that has the ability to absorb water and increase its size in volume. (Dkt. 483)
7	Special Master's Suggested Construction on June 22, 2015	"a gelling agent made from polyacrylic acid which has been cross-linked to form a non-dimensionally stable material that in the salt form has the ability to absorb large quantities of water and increase many times its size in volume" (Dkt. 456 at 44)
8	Defendants' current proposed construction	Indefinite (Dkt. 532 at 10)
9.	Special Master's Suggested Construction on October 24, 2016	A gelling agent made from polyacrylic acid which has been cross-linked with a suitable cross-linking agent (cross-linker) at an amount of less than 10% (w/w) to form a non-dimensionally stable material that has the ability to absorb water and increase its size in volume. (Dkt. 541 at 2)

In this supplemental round of claim construction, Plaintiffs proposed a construction that admittedly “fused” the Special Master’s construction with their prior construction. (Dkt. 531 at 15). The construction now recommended by the Special Master is the fused construction with a higher percentage weight-to-weight ratio of crosslinking agent (the Special Master adopts a less than 10% numerical boundary rather than 5% proposed by Plaintiffs) (541 at 13-14).

### **III. LEGAL STANDARDS**

#### **A. Standard of Review**

The Court must decide *de novo* Defendants’ objections to the Special Master’s findings of fact and legal conclusions. Fed. R. Civ. P. 53(f)(3)-(4). The Court “may adopt or affirm, modify, wholly or partly reject or reverse, or resubmit to the master with instructions.” Fed. R. Civ. P. 53(f)(1).

#### **B. Claim Construction**

The construction of patent claims is a legal matter for the court to decide. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). “[T]he words of a claim ‘are generally given their ordinary and customary meaning,’ ” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed.Cir.2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)), which “is the meaning that the term would have to a

person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1313. “[C]laims ‘must be read in view of the specification, of which they are a part.’” *Id.* at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996)).

Claim construction begins with the intrinsic evidence of the patent-the claims, the specification, and the prosecution history-and may require consultation of extrinsic evidence to understand the state of the art during the relevant time period. *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history." *Markman*, 52 F.3d at 980. Such evidence typically includes dictionaries, treatises, and testimony of the inventor or experts. *Id.*; (Dkt. 541 at 7). Extrinsic evidence, however, is "less significant than the intrinsic record in determining the legally operative meaning of claim language," and is appropriate only when the available intrinsic evidence is not dispositive. *Phillips*, 415 F.3d at 1317, 1320-21 (internal quotation marks omitted). When considering extrinsic evidence, a court should take care not to use it to vary or contradict the claim terms. *Id.* Indefiniteness is a legal issue evaluated by a court as part of “its duty as the construer of patent claims.” *In re Aoyama*, 656 F.3d

1293, 1299 (Fed. Cir. 2011); *see also Teva*, 135 S. Ct. at 836-37 (analyzing indefiniteness in context of claim construction).

### **C. Indefiniteness**

The claims of a patent must “particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention.” 35 U.S.C. § 112(b). In *Nautilus*, the Supreme Court held: “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, *with reasonable certainty*, those skilled in the art about the scope of the invention.” *Nautilus*, 134 S. Ct. at 2124 (emphasis added). This inquiry “trains on the understanding of a skilled artisan at the time of the patent application,” *Id.* at 2130, and asks whether “[the] patent [is] precise enough to afford *clear notice* of what is claimed, thereby apprising the public of what is still open to them.” *Id.* at 2129 (citation omitted)(emphasis added); *See also Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003) (definiteness requirement assures that the claims are “sufficiently precise to permit a potential competitor to determine whether or not he is infringing”).

It is not sufficient that “a court can ascribe *some* meaning to a patent’s claims.” *Nautilus*, 134 S. Ct. at 2130 (emphasis in original) Rather, “[t]he claims, when read in light of the specification and the prosecution history, *must provide*

*objective boundaries* for those of skill in the art." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014)(emphasis added). *See also Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008) ("The fact that [the patent holder] can articulate a definition supported by the specification... does not end the inquiry. Even if a claim term's definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope.").

The question of indefiniteness is ripe for resolution when it arises as part of a disputed claim term during the claim construction process. *See How Medica Osteonics Corp. v. Tranquil Prospects, Ltd.*, 401 F.3d 1367, 1371 (Fed. Cir. 2005). Courts have repeatedly held claims indefinite as a matter of law when they have been unable to discern the scope of the claims at the *Markman* stage.<sup>6</sup>

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<sup>6</sup> *Interval Licensing LLC*, 766 F.3d at 1364 (affirming district court's holding at *Markman*/claim construction phase that claim was indefinite); *Triton Tech of Texas LLC v. Nintendo of America, Inc.*, 753 F.3d 1375 (Fed. Cir. 2014 )(same); *Function Media, LLC v. Google Inc.*, 708 F.3d 1310 (Fed. Cir. 2013) (same); *Noah Systems, Inc. v. Intuit, Inc.*, 675 F.3d 1302 (Fed. Cir. 2014) (affirming district court's holding at the *Markman*/claim construction phase that claim was indefinite and therefore summary judgment was proper); *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008) (same where the claim term at issue was "fragile gel").



#### IV. ARGUMENT

##### A. The Special Master Erred By Applying A Pre-*Nautilus* Standard To The Indefiniteness Inquiry At Claim Construction.

During the Supplemental Claim construction proceeding, the Special Master repeatedly alleged the mandate of this Court was to “come up with what is the best description” and a construction of the Lightly Crosslinked Limitation:

**Special Master:** And we have been mandated by the Judge to reconsider this and to come up with what is the best description and construction of this term.

**Special Master:** We've been mandated by Judge May, and I believe correctly so, to get into a room and come up with the answer to the claim construction on lightly cross-linked polyacrylic acid polymer, and I think we are all here to do that today...

(Exhibit A at 151: 3-5; 162 3-5): The Special Master misunderstood the mandate of this Court was to propose a construction at all costs. *See* Dkt. 490 at 19, note 5 “the Court is mindful however, that Special Master should construe the claims to preserve validity, **if possible**” (emphasis added); Dkt. 530 at 4). However, the “presumption of validity does not alter the degree of clarity that § 112, ¶ 2 demands from patent applicants.” *Nautilus*, 134 S. Ct. at 2130.<sup>7</sup>

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<sup>7</sup> Even before *Nautilus*, the Federal Circuit held that doctrine of construing claims to preserve their validity is of “limited utility” and is not without limits. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1328 (Fed. Cir. 2005). The Federal Circuit has cautioned repeatedly that doctrine should not be invoked to do what was the Special Master would have this Court do – rewrite claim terms. *Id.*; *see also E.I.*

This Court expressly stated that in light of the extensive claim construction “history alone, this Court cannot say as a matter of law that the relevant terms are amenable to construction.” (Dkt. 530 at 4). The Court further instructed that the Special Master should consider the Defendants’ indefiniteness arguments to determine whether the claim term is amenable to construction, and if so, what construction is appropriate. *Id.*

The Special Master gave short shrift to the consideration of whether the Lightly Crosslinked Limitation was amenable to construction and proceeded instead to the task of weaving together third-party patents and expert testimony to arrive at *some* construction:

“And then we have testimony from an expert, who is the only expert in the room, who is saying that he accepts five percent but is not entirely comfortable with it and he thinks there are lightly cross-linked polyacrylic acids up to ten percent. And so how you meet that is the functional definition which is in here. And it sounds like that’s consistent **if we’re trying to thread all the needles we have with all the patents that we have and all the expert testimony that we have available to us today**, you know, tell me what’s wrong with that.”

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*du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1434 (Fed.Cir.1988) (rejecting argument that limitations should be added to claims to preserve the validity of the claims); *Generation II Orthotics Inc. v. Med. Tech. Inc.*, 263 F.3d 1356, 1365 (Fed.Cir.2001) (“[C]laims can only be construed to preserve their validity where the proposed claim construction is ‘practicable,’ is based on sound claim construction principles, and does not revise or ignore the explicit language of the claims.”).

(Exhibit A, 155:18-156:2). Post-*Nautilus*, however, it is not sufficient that an expert and a court can come in and ascribe *some* meaning to a patent's claims. *Nautilus*, 134 S. Ct. at 2130. Instead, the court must ask whether a person of ordinary skill, after reading the specification and prosecution history, would be reasonably certain of the correct scope of the claim. *Id.* A claim fails the "reasonably certain" standard if "a person of ordinary skill would determine that there are multiple equally plausible but materially dissimilar constructions of a claim term", even "if none of the competing constructions are 'insolubly ambiguous.'" *Diamond Coating Techs., LLC v. Hyundai Motor Am.*, No. 8:13-CV-01480-MRP, 2014 WL 5698445, at \*4 (C.D. Cal. Aug. 25, 2014).

The Special Master did not consider whether and why a POSA (Dr. Bowman) can and did come to conflicting constructions. During Defendants' counsel's cross of Dr. Bowman, the Special Master refused to allow a line of questioning that goes to the heart of whether the Lightly Crosslinked Limitation has reasonably a certain meaning to a POSA, going as far as to withdraw questions asked by counsel:

- Q. You thought your original construction was supported by the record, didn't you?
- A. I did and still do believe that my original construction was supported by the record, but the record now, the record at that

time, the record now includes the instructions from the Special Master and the Judge which this reflects.

Q. Absent those orders, would you revert back to original construction?

A. I believe that the original construction was what one of – ordinary skill in the art in the absence of the Court's instructions would have come with, and that's why I did.

Q. So this change doesn't have literature support?

A. So it depends what you mean by literature. I think an instruction from the Judge and Special Master is literature. It's not scientific literature necessarily but it's literature, and you know, it's something that we've something we've been instructed to follow.

Q. As you understand it, of one of ordinary skill in the art, and— are the Court's orders binding on within this jurisdiction and across the United States?

A. I'm not sure that's a scientific question that I can answer. I don't know what the –

Special Master: I don't think that's appropriate

By Mr. Acharya

Q. Okay. So if one of ordinary – so if was sitting in Wisconsin, would my construction—

**Special Master: That's a legal question, so I think if you limit your questions to scientific questions, not legal questions.**

By Mr. Acharya:

Q. **In your experience does one of ordinary skill in the art turn to legal opinions to construe terms?**

Special Master: No.

Special Master: **No. Withdrawn. You don't have to answer that.**

(Ex. A, 143:19-145:5) (emphasis added).

Defendants respectfully submit that the line of questioning was proper and that what Defendants' counsel was trying to elicit was not a legal opinion, but rather why a POSA would alter an original construction if the claim term had a plain and ordinary meaning that would be known with reasonable certainty to those with skill in the art. The Special Master's refusal to consider the issue or even to allow a line of questioning with respect to it was error and underscores her myopic focus on arriving at *some* construction, contrary to the mandates of *Nautilus* and its progeny.

The Special Master appeared willing to ignore evidence that a meaning of a claim term can and was changed by Plaintiffs' expert based on the "unpredictable vagaries of any one person's opinion," highlights the fact that this claim term is ambiguous. *See Interval Licensing*, 766 F.3d at 1374 ("The specification offers no indication, thus leaving the skilled artisan to consult the "unpredictable vagaries of any one person's opinion"). If the Lightly Crosslinked Limitation had an established meaning in the art, a POSA could not and would not change their definition based on the concerns of a Court or a Special Master. *See Nautilus*, 134

S. Ct. at 2123 (“[P]atents are not addressed to lawyers or to the public generally but to those skilled in the relevant art”) (internal citations and quotations omitted).

**B. The Special Master Erred By Arbitrarily Adopting One Of Multiple Possible Metrics to Measure A Term Of Degree.**

The Special Master erred by arbitrarily adopting **some** standard of measurement for a term of degree “lightly” when multiple metrics are possible and yield different results. When a patent claim uses a term of degree, such as “lightly,” “it is not enough ... to identify ‘some standard for measuring the scope of the phrase.’” *Interval Licensing*, 766 F.3d at 1370-71. Rather, “[t]he claims, when read in light of the specification and prosecution history, must provide objective boundaries for those of skill in the art.” *Id.* If the intrinsic evidence fails to set forth any such objective standard, leaving persons of skill to guess as to the meaning of the term of degree, then that claim term is invalid for indefiniteness. *KLATencor Corp. v. Xitronix Corp.*, No. 09-ca-723, 2011 WL 318123, at \*3 (W.D. Tex. Jan. 31, 2011)

The Federal Circuit has noted the definiteness problems which arise when “words of degree” are used in a claim. *Seattle Box Co. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed.Cir.1984).

Definiteness problems often arise when words of degree are used in a claim. That some claim language may not be precise, however, does not automatically render a claim invalid. **When a word of degree is**

**used the district court must determine whether the patent's specification provides some standard for measuring that degree.**

*Id.* (emphasis added). Although terms of degree are common in patent law, post-*Nautilus*, “although absolute or mathematical precision is not required, it is not enough, as some of the language in our prior cases may have suggested, to identify some standard for measuring the scope of the phrase.” *Interval Licensing*, 766 F.3d at 1370–71 (holding term of degree indefinite).

The Federal Circuit’s post-*Nautilus* opinion in *Dow Chemical Co. v. Nova Chemicals Corp.* (Canada), 803 F.3d 620 (Fed. Cir. 2015), is instructive. In *Dow*, the Federal Circuit reconsidered claims it previously held definite in light of the Supreme Court’s intervening decision in *Nautilus*. *Id.* at 624. The claims at issue in *Dow* involved ethylene polymer compositions having properties permitting them to be made into thinner films having greater strength than conventional films. *Id.* The claim term at issue defined this property, wherein the composition had “a slope of strain hardening coefficient greater than or equal to 1.3.” *Id.* at 624-25. The evidence in record showed that there were multiple methods to measure the measure the value of the coefficient and therefore the question before the court was “whether the existence of multiple methods leading to different results without guidance in the patent or the prosecution history as to which method should be used renders the claims indefinite.” *Dow*, 803 F.3d at 634. The answer is yes.

In arriving at its decision, the *Dow* court noted that, prior to *Nautilus*, “a claim was not indefinite if someone skilled in the art could arrive at a method and practice that method”, the Court held that “post-*Nautilus*, this is no longer sufficient.” *Dow*, 803 F.3d at 634. Thus, while the claims were definite pre-*Nautilus*, they did not pass muster post-*Nautilus* because the “required guidance” as to *which measurement* should be used was “not provided by the claims, specification, and prosecution history.” *Id.* The fact that patentee’s expert was able to testify that someone skilled in the art could determine which method was most appropriate or best to measure the coefficient- as Dr. Bowman did here with respect to cross-linking density – was not enough to save the claims or provide the requisite certainty. *Id.*

Similarly, in *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335 (Fed. Cir. 2015), the Federal Circuit considered whether the term “molecular weight” was reasonably certain and concluded that because three relevant measures for molecular weight—peak average molecular weight (“M<sub>p</sub>”), number average molecular weight (“M<sub>n</sub>”), and weight average molecular weight (“M<sub>w</sub>”)—where each was calculated in a different manner and each typically had a different value, the term was indefinite. *Id.* at 1338. This was the case even though the patentee’s



expert – again like Dr. Bowman here - testified that someone skilled in the art could determine which method was the most appropriate. *Id.* at 1338, 1341.

Here, there can be no dispute that there is more than one way to measure whether a polymer is lightly cross-linked to practice the invention taught in the ‘383 Patent. (*Compare, e.g.,* Exhibit D with 541 at 2). One court has already decided that cross-linking density is best measured in terms of viscosity, finding that “after examining the specification, the Court finds that it is entirely appropriate to define ‘lightly cross-linked’ polyacrylic acid polymers by reference to their viscosity.” (See Exhibit E, (Report and Recommendation in *Medicis*) at 17-18 (D. Del. June 12, 2012). While the monomer to cross-linking weight ratio measurement now advanced by Dr. Bowman is described by him to be the **best** way to measure cross-linking density (Exhibit F, Bowman Dep. 142:13-18), there can no legitimate contention that it is the **only** way. Moreover, like the different methods of measurement at issue in *Dow*, the different methods of measurements here yield two very different results. Specifically, the viscosity measurement adopted in *Medicis* excludes certain CARBOPOLS while the construction advanced by Plaintiffs and the Special Master spans the entire class of

CARBOPOL polymers.<sup>8</sup> Accordingly, like the claim terms in *Dow* and *Teva*, the Lightly Crosslinked Limitation should be held indefinite.

Although Special Master states that any POSA would know what the Lightly Crosslinked Limitation means, the conflicting constructions of Plaintiffs' expert (based on the same extrinsic evidence) belies any genuine question as to whether the Lightly Crosslinked Limitation informs a POSA with the requisite reasonable certainty as to the scope of invention. As a district court judge in Delaware observed under similar facts in an order invalidating terms of degree in another one of Plaintiff's patents:

In addition, the conflicting interpretations of the disputed term offered by Dr. Shulman in his two declarations underscore the fact that the patent "fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention," Bayer contends that Dr. Shulman's supplemental declaration and the extrinsic evidence demonstrate a "known industry standard" or an "established meaning in the art." **But Bayer's change of course shows this argument to be specious. As [Defendant] states, if there were actually an "established meaning in the art," Dr. Shulman would have identified it in his original declaration.**

*Bayer Intellectual Prop. GmbH v. Warner Chilcott Co., LLC*, No. CV 12-1032-GMS, 2015 WL 1849015, at \*3 (D. Del. Apr. 21, 2015), *aff'd sub nom. Bayer*

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<sup>8</sup> See Dkt. 541 at 23, finding that CARBOPOLS have .75 to 2% (w/w) cross-linker and are considered "lightly cross-linked."

*Intellectual Prop. GmbH v. Warner Chilcott Co., LLC*, No. 2015-1716, 2016 WL 1426033 (Fed. Cir. Apr. 12, 2016).

The construction now advanced by Special Master is not, according to Plaintiff's expert, the best construction of the term. (Exhibit A, 143 -145). Instead, the construction is a fusion of the Special Master's proposed construction and the Plaintiff's initial proposed construction, both of which were rejected by this Court (Dkt. 490, 530). If the Lightly Crosslinked Limitation had a known established meaning certain to those with skill in the art, multiple constructions and compromised definitions would not be necessary.

**C. The Special Master Erred By Relying On Extrinsic Evidence and Expert Testimony To Arrive At A Construction That Is Divorced From The Intrinsic Evidence, Violating Claim Construction Principles in the Process.**

The Special Master improperly relied on expert testimony and extrinsic evidence to arrive at a construction that not only is not supported by the intrinsic record, but contradicts it. Although the Special Master makes repeated references to Dr. Bowman as the only expert to testify at the supplemental claim construction hearing (Dkt. 541 at 7; Exhibit A, 155:19), that does not make his testimony the unequivocal truth or demand blind acceptance by the Special Master or this Court. *See, e.g., Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed.Cir.1997) (affirming district court's determination despite unrebutted expert testimony to the

contrary because “[n]othing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness”); *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 147 F.3d 1374, 1379 (Fed. Cir. 1998) (“The fact that Applied Medical did not contest this point with testimony from one of its own experts no more resolves the factual question in Surgical's favor....”).

**1. The Special Master Advances A Construction That Incorporates A Metric She Previously and Correctly Rejected**

What is most remarkable about the construction the Special Master now advances, is that she previously and unequivocally rejected the core of it when it was proposed by Plaintiffs. (*See* Dkt. 456 at 46). In her initial report and recommendation, the Special Master found that Plaintiffs’ proposed construction of ‘a polyacrylic acid polymer cross-linked with a suitable cross-linking agent (cross-linker) at an amount less than about 5-10% (w/w)’ “does not find support in the intrinsic or extrinsic record.” (Dkt. 457 at 46). She further found Dr. Bowman’s reference to the 5-10 w/w% “conclusory and clearly at odds with the construction mandated by the claims themselves...” as **“nowhere in the ‘383 Patent is the concept of a weight monomer to cross-linking agent hinted at.”** (*Id.*) (emphasis added).

The Special Master now recommends that this Court adopt a construction that incorporates the weight-to-weight measurement she previously, and correctly, rejected as entirely untethered to the evidence. (Dkt. 457 at 46). Not only was the Special Master correct that the concept of the measuring cross-link density by weight monomer to cross-linking agent absent from the claims, the specification or the prosecution history, it conflicts with the intrinsic record, which measures cross-linking density solely in terms of viscosity. (*See, e.g.*, '383 Patent, col. 4, ll. 34-36). (*See also* Exhibit E, *Medicis Report and Recommendation on Claim Construction*, at 19-20 (“by describing a polymer as “lightly cross-linked,” the patent is also inherently describing it as having lower viscosity than a polymer with more cross-links in the same concentration in an aqueous solution... [r]ather than reading the term ‘lightly’ out of the claim language, Defendant's proposal goes to the heart of what ‘lightly’ means, according to the '383 patent... the patent repeatedly indicates that an upper limit on viscosity is the only appropriate way to ascribe meaning to the claim limitation at issue”)).

Although the Special Master and this Court may rely on extrinsic evidence at claim construction, the Federal Circuit has repeatedly cautioned its use to because “extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is

not present in intrinsic evidence” and “there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question.” *Phillips*, 415 F. 3d at 1318. [U]ndue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the ‘indisputable public records consisting of the claims, the specification and the prosecution history,’ thereby undermining the public notice function of patents.” *Id.* at 1318-19 (citing *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995); *see also Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1361 (Fed. Cir. 2005) (rejecting patentee's expert's proposed construction of disputed claim term because the expert's opinion was just a conclusory statement where the expert failed to “support his conclusion with any references to industry publications or other independent sources” and because his testimony was at odds with the intrinsic evidence, mainly the description of the invention in the specification, it therefore had to be disregarded—affirming summary judgment of no infringement).

The Special Master’s undue reliance on expert testimony and extrinsic evidence to provide objective boundaries and measurement methods that are nowhere in the patent itself, causes the particular harm warned of in *Philips* by rewriting claim terms in derogation of the public notice function of patents, later

underscored in *Nautilus*, which requires a patents claims to point out and distinctly claim what is covered and what is not. The inventors of the ‘383 Patent failed to do so. And neither the Plaintiffs’ expert, nor the compilation of prior art references, nor the Special Master can come in *post hoc* and supply boundaries missing from the claim term.

**2. The Extrinsic Evidence Does Not Support The Special Master’s Factual Findings Regarding The Lightly Crosslinked Limitation.**

The Special Master found that the term “lightly cross-linked” was “regularly used as a term of art in the polyacrylic acid polymer field.” (Dkt . 541 at 23). In support, the Special Master cites six third-party patents,<sup>9</sup> three of which do not use the term “lightly-cross linked” at all. (*See* U.S. Pat. No. 5,858,340 (Dkt. No. 531-8), PCT Publ. No. 2009/023393 (Dkt. No. 531-9), and U.S. Pat. Reissue No. 29,814 (Dkt. No. 531-10))). And, as admitted by the Special Master, not one of these six references support the numeric range advanced by Plaintiffs - less than 5% (w/w)- or what she now recommends - less than 10% (w/w) – as the “described weight percentages are no more than 2%. (Dkt. 541 at 23).

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<sup>9</sup> Specifically, the Special Master cites U.S. Pat. No. 5,858,340 (Dkt. No. 531-8), PCT Publ. No. 2009/023393 (Dkt. No. 531-9), and U.S. Pat. Reissue No. 29,814 (Dkt. No. 531-10)), (U.S. Pat. No.5,939,094 (Dkt. No. 531-13), U.S. Pat. No. 5,827,247 (Dkt. No. 531-14), and U.S. Pat. No. 4,837,378 (Dkt. No. 531-15).

The Special Master's factual finding that "lightly cross-linked" is a term of art regularly used in the field of polymer science is belied by the expert testimony upon so much of her recommendation depends. (Dkt. 541 at 4). Yet, Dr. Bowman, who has been studying cross-linked polymers for nearly 30 years (Exhibit A, 45:13-15), cannot ever recall using the term "lightly cross-linked" in any of his hundreds of published papers (Exhibit A, 117:10-11). Nor can Dr. Bowman recall ever using it in his classroom (Exhibit A, 119:21-24). Dr. Bowman has been unable to find the term defined in a single textbook or research article. (Exhibit A, 120:3-14).

**3. The Special Master's Construction Improperly Imports Numerical Ranges Into Descriptive Claim Terms**

The Special Master compounds her error by proposing a construction that imports numeric limitations into claim terms that are not only not in the claims themselves or derived from the specification, they are derived from a measurement metric (w/w) that, as she previously observed, is not even hinted at the Patent. (Dkt. 457 at 46). Thus, the Special Master is farther beyond removed from what the Federal Circuit has already deemed is generally unacceptable, reading numerical ranges from the specification. She is reading in numerical ranges into the claims from other patents cited nowhere in the '383 Patent.

The Federal Circuit has repeatedly held "when a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical



range that may appear in the written description or in other claims.” *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349, 1358 (Fed. Cir. 2006) (rejecting construction of “water-alcohol” mixture to have at least 30% water based on a statement in the specification generally describing a claimed compound as having 0-70% because that statement described a preferred embodiment and did so only in generality). The imprecision allowed by reading numerical limitations into terms of degree is precisely why numerical ranges are typically not imported in construing terms of degree. *See Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 907 (Fed. Cir. 2005) (“But the definition of ‘substantially flattened surfaces’ adopted by the district court introduces a numerical tolerance to the flatness of the gripping area surfaces of the claimed applicator [which] contradicts the recent precedent of this court, interpreting such terms of degree.”) (citing *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1361 (Fed. Cir. 2003); *Anchor Wall Sys. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1311 (Fed. Cir. 2003)).

Descriptive terms of terms of degree are commonly used by patentees to avoid an imposition of strict numerical boundary. *Id.* If the inventors wanted a strict numerical boundary in the Lightly Crosslinked Limitation they could have put one. However, absent any indication in the claims, the specification or the

prosecution history that the inventors did not want to encompass any polymers that were cross-linked with an agent that was 10.1% or above w/w, the Special Master neither the Special Master nor this Court should write in such a limitation.

Moreover, although the Special Master cites *Modine* in support of her importation of a numerical range, the numerical range imported in that case and every other case in the very limited situations where numerical ranges have been read into claim terms, the numeric ranges were taken from the specification or other claim terms – that is, they were somewhere in the intrinsic record itself. *See Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1552 (Fed. Cir. 1996); *see also Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1170–71 (Fed. Cir. 2012) (“although the claim language itself is a qualitative measure, the claim construction pulls directly from the specification to give the term “substantially all” a quantitative definition”).

Here, the claim specification does even contain the measurement to metric to get to the numerical range the Special Master would have this Court import into Lightly Crosslinked Limitation.

**D. The Special Master Erred By Not Finding The Lightly Crosslinked Limitation Is Indefinite.**

The extensive claim construction history regarding the Lightly Crosslinked Limitation reveals a host of factors, that taken together, compel a single

conclusion. There is no reasonably certain delineation of the metes and bounds of the Lightly Crosslinked Limitation to a person of ordinary skill in the art (POSA) and the Lightly Crosslinked Limitation is therefore indefinite.

The patent claims, specification and prosecution history do not provide an explicit definition of the Lightly Crosslinked Limitation (Exhibit A, 127:23-24). Although Plaintiff (and now the Special Master) suggest the term "lightly cross linked polyacrylic acid polymer" has a plain and ordinary meaning in what is an important and longstanding field of science, it is undisputed the expert on which the Special Master depends for so much of her construction of the Lightly Crosslinked Limitation has never used the term himself, nor has he used it in a paper or in his classroom. (Exhibit A, 117-120). For illustration, the record shows that are at least three ways to measure the degree of cross-linking that a person of ordinary skill in the art would use to determine whether a polymer is "lightly" cross-linked:

- viscosity ( Exhibit D at ¶ 3);
- mole percentage (Exhibit F, Bowman Dep. 143:2-4);
- weight to weight monomer to cross-linking agent (Dkt. 541 at 2).

The Special Master's latest proposed construction of the Lightly Crosslinked Limitation is merely the latest in a litany of attempts to ascribe some meaning to

the Lightly Crosslinked Limitation. (*See* Table in Section II, setting forth the nine different constructions advanced by Courts and litigants in this case and *Medicis, supra*). All of the constructions have been supported by expert testimony or prior art references. (*Id.*) One construction – which differs significantly from the construction now advanced by the Special Master - has been adopted by a district court in Delaware. (*Id.*) The Special Master’s latest proposed construction of the Lightly Crosslinked Limitation is merely the latest in a litany of attempts to ascribe some meaning to the Lightly Crosslinked Limitation.

Finally, a review of the record, including the inventor’s testimony regarding where the term was derived, sheds some light on the struggle. Two of the three inventors of ‘383 Patent, Dr. Gordon J. Dow (“Dr. Dow”) and Robert Lathrop were deposed in *Medicis* case regarding the Lightly Crosslinked Limitation.<sup>10</sup> Dr. Dow,

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<sup>10</sup> Portions of this testimony accompanied Defendants’ Supplemental Brief on Claim Construction [Dkt. 385]. While the excerpts from the transcripts of the Depositions Dr. Gordon Dow [Dkt. 385-1] and Robert Lathrop [Dkt. 385-5] take in the *Medicis* litigation themselves were filed under seal pursuant to the Court’s Stipulated Amended Protective Order [459], the content of certain portions of the transcript appear in the filed brief itself and are cited here for ease of reference.

<sup>10</sup> (Dow *Medicis* Dep. 185:9-15; Lathrop *Medicis* Dep. 74: 11-15, 80:17-20 *Medicis Pharmaceutical Corp. et al. v. Actavis Mid Atlantic LLC*, No 11-409, LPS-CJB (D. Del) ("*Medicis*"),

the primary inventor testified that he took the term lightly cross-linked from B.F. Goodrich's marketing literature:<sup>11</sup>

Q. How did that terminology ["lightly" cross linked and highly cross linked] get into your patent then?

A. ...So we used the literature from B.F. Goodrich, who was the supplier at the time, and what we could learn from their literature and used that primarily [as] the descriptive information in the patent.  
So it's their terminology we have adopted.

(Dow *Medicis* Dep. p. 185). Thus, the parties and Special Master have been attempting to construe a non-scientific marketing term that the record reflects had no consensus meaning to person of ordinary skill in the art.

## V. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court set aside the Special Master's construction of "lightly crosslinked polyacrylic acid polymer" and hold the Lightly Crosslinked Limitation indefinite.

Dated: November 17, 2016

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<sup>11</sup> (Dow *Medicis* Dep., 185)

BAKER, DONELSON, BEARMAN,  
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**CERTIFICATE OF COMPLIANCE**

Undersigned counsel certifies the foregoing document has been prepared with one of the font and point selections (Times New Roman, 14 Point) approved by the Court in Local Rule 5.1 (C) and 7.1 (D).

This 17th day of November, 2016.

BAKER, DONELSON, BEARMAN,  
CALDWELL & BERKOWITZ, P.C.

/s/ Robert G. Brazier

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**CERTIFICATE OF SERVICE**

I hereby certify that on November 17, 2016 I electronically filed **DEFENDANTS' OBJECTION TO THE SPECIAL MASTER'S REPORT AND RECOMMENDATION ON SUPPLEMENTAL CLAM CONSTRUCTION** with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all counsel of record.

This 14th day of November, 2016.

/s/ Robert G. Brazier

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